

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	CIV. NO.05-73407
)	
v.)	HONORABLE DENISE PAGE HOOD
)	
Various blood glucose test)	MAGISTRATE JUDGE STEVEN D. PEPE
strips(BGTS), etc.)	
)	
)	
Defendants.)	

CONSENT DECREE OF CONDEMNATION AND DESTRUCTION

WHEREAS, on September 2, 2005, the United States of America ("Plaintiff"), by and through its attorney, Stephen J. Murphy, United States Attorney for the Eastern District of Michigan, filed a verified Complaint for Forfeiture ("Complaint") in this Court against the above-captioned articles, which alleges that said articles are adulterated and/or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act ("the Act");

WHEREAS, the United States Marshal for this District seized the above-captioned articles pursuant to a Summons Warrant of Arrest of Property and Notice In Rem issued by this Court;

WHEREAS, on September 30, 2005, H&H Wholesale Services, Inc. and Door to Door Medical Supply, Inc. (collectively, "Claimant") intervened and filed a Claim to all of the seized articles;

WHEREAS, a Consent Decree of Condemnation was previously signed by the parties and entered by this Court with respect to the three lots of ONETOUCH ULTRA blood glucose test strips that were seized on September 2, 2005 at 333 Park Street, Troy, Michigan;

WHEREAS, a second Consent Decree of Condemnation was signed by the parties and entered by this Court with respect to the ONETOUCH ULTRA blood glucose test strips that were seized on September 2, 2005 at 6775 East Ten Mile Road, Centerline, Michigan;

WHEREAS, this Consent Decree of Condemnation and Destruction (hereafter, "Consent Decree" or "Decree") pertains to the seized ACCU-CHEK ACTIVE and ACCU-CHEK COMPACT blood glucose test strips (hereinafter, "the Articles");

WHEREAS, Claimant affirms that it is the sole owner of the Articles, that no other person has an interest in the Articles, and that it will indemnify and hold Plaintiff harmless should any party or parties hereafter file or seek to file a statement of interest, or to intervene in this action and obtain or defend any part of the Articles subject to this Decree;

WHEREAS, Claimant, without admitting the allegations in the Complaint, now consents to the entry of this Consent Decree without contest and before any testimony has been taken; and

WHEREAS, Plaintiff consents to the entry of this Consent Decree, and the Court being fully advised of the basis thereof, it is now ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334.

2. The Articles are misbranded within the meaning of 21 U.S.C. § 352(c) in that words, statements, or other information required by 21 C.F.R. § 809.10 to appear on the label or labeling are not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

3. The Articles are hereby condemned pursuant to 21 U.S.C. § 334, and forfeited to Plaintiff.

4. Pursuant to 21 U.S.C. § 334(e), Claimant shall pay to the United States all court costs and fees, storage, and other proper expenses to date, and such additional expenses as may hereinafter be incurred and taxed.

5. Within fifteen (15) days of the entry of this Consent Decree, Claimant shall: (a) pay in full the court costs, storage, and other proper expenses of this proceeding incurred to date, as set forth in paragraph 4 of this Decree; and (b) execute and file with the Clerk of this Court a good and sufficient penal bond

with surety in the amount of ten thousand dollars (\$10,000.00). Claimant shall satisfy the requirement of filing a penal bond by depositing ten thousand dollars (\$10,000.00) into the registry of this Court. The funds shall be deposited in accordance with Rule 67 of the Federal Rules of Civil Procedure, and applicable statutes and local rules. The Clerk of Court shall deposit the funds in an interest bearing account, pursuant to Local Rule 67.1, and shall deduct from the account any fee authorized by the Judicial Conference of the United States. Release of the funds to Claimant shall occur upon Court order following Claimant's abiding by and performing the terms and conditions of this Decree.

6. After paying the costs pursuant to paragraph 4 and depositing the funds into the registry of this Court as specified in paragraph 5, Claimant shall give written notice to FDA at the Detroit District Office, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207, that Claimant, at its own expense, is prepared to destroy the Articles, pursuant to 21 U.S.C. § 334, under the supervision of a duly authorized representative(s) of the United States Department of Health and Human Services ("FDA representative"). Claimant's notice shall specify the proposed time, place, and method of destruction of the Articles.

7. Claimant shall not commence attempting to destroy the Articles until Claimant has received written authorization to commence with the destruction from an FDA representative. All Articles shall be destroyed at Claimant's expense under the supervision of an FDA representative. Claimant shall pay to the United States all costs incurred in supervising the destruction of the Articles, at the rates specified in paragraph 13 of this Decree.

8. Following receipt of notice from FDA that Claimant has paid the costs pursuant to paragraph 4, deposited the funds into the registry of this Court as specified in Paragraph 5, and submitted notice to FDA pursuant to paragraph 6, and that FDA has issued the written authorization pursuant to paragraph 7, the United States Marshal for this District shall release the Articles from his custody to the custody of Claimant for the sole purpose of destroying the articles.

9. Claimant shall not destroy or dispose of, permit another person to destroy or dispose of, or cause another person to destroy or dispose of the Articles or any part of the Articles in a manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act), in which they are disposed of.

10. Claimant shall at all times, until the Articles have been destroyed, retain the Articles intact for examination or inspection by the FDA representative, and shall maintain the records or other proof necessary to establish the identity of the Articles to the satisfaction of the FDA representative.

11. Within forty-five (45) days of entry of this Decree, Claimant shall complete the destruction of the Articles under the supervision of FDA. Within fifteen (15) days of Claimant's completion of the destruction of the Articles, FDA will send Claimant an invoice for the costs of supervising such destruction, and Claimant shall pay those costs within ten (10) days of receiving FDA's invoice.

12. The United States Attorney for this District, upon being advised by an FDA representative that the Articles have been destroyed in compliance with this Decree and the law, and that Claimant has paid all costs as of that date, will transmit such information to the Clerk of this Court, whereupon the funds deposited in the registry of this Court shall be returned upon Court order.

13. Claimant shall reimburse the United States for the costs of supervising Claimant's compliance with the terms of this Decree, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at

the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, these rates are: \$76.10 per hour and fraction thereof per representative for inspection work; \$91.18 per hour and fraction thereof per representative for analytical work; \$0.445 per mile for travel expenses; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative, for subsistence expenses where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court.

14. If Claimant fails to abide by and perform all of the terms and conditions of this Decree, then the funds deposited as provided in Paragraph 5 of this Decree shall, on motion of Plaintiff in this proceeding and order of the Court, be forfeited in their entirety and judgment entered in favor of Plaintiff. If Claimant breaches any term or condition of this Decree, then Claimant at its own expense, shall immediately return the Articles to the United States Marshal for this District or otherwise dispose of them pursuant to an order of this Court. In the event that return of the Articles becomes necessary pursuant

to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by Plaintiff.

15. Claimant shall abide by the decisions of FDA, which shall be final. All decisions specified in this Decree shall be vested in the discretion of FDA. When contested by Defendants, FDA decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard, 5 U.S.C.

§ 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

16. Except as expressly provided to the contrary in this Consent Decree, each party shall bear its own legal and other costs incurred in connection with this matter.

17. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

SO ORDERED:

Dated this 19th day of September, 2007

s/ DENISE PAGE HOOD
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree.

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